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EXAMINER

NOLAN, P

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/392,024

Applicant(s)  
Riser et al.

Examiner  
Patrick Nolan

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 13, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

**Part III DETAILED ACTION**

1. This application is a continuation-in-part of 60/099,471 and 60/112,855.

2. The specification on page 1 should be amended to reflect the claim to domestic priority under 35 USC 119(e), serial numbers 60/099,471 and 60/112,855.

3. Claims 1-18 are pending.

4. Applicant's election with traverse of Group IX, claims 14-18 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden on the Examiner to examine all the groups together. This is not found persuasive for the reasons set forth in Paper No. 6.

The requirement is still deemed proper and is therefore made FINAL.

However, upon further reconsideration the Species election set forth in Paper No. 6 has been removed.

5. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 and its dependent claims are rejected as being indefinite because for one of skill in the art to practice the claimed invention, a detection assay, the claim must include a resolution step, wherein the detection of the level of CTGF and comparing said level with a standard level of CTGF would lead one of skill in the art to determine that if increased levels of CTGF are detected when compared to normal levels the subject has a renal disorder characterized by overproduction of extracellular

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/38172.

The '172 patent teaches a method of detecting kidney fibrosis (i.e. a disease caused by overproduction of extracellular matrix) by detecting CTGF and comparing said detection to a standard (page 3 and 7, in particular). Claim 15 is included in the rejection because diabetes is art recognized to cause kidney fibrosis, prior to applicant's claimed invention.

The prior art teachings anticipate the claimed invention.

7. Claims 14 and 15 are rejected under 35 U.S.C. § 102(a) as being anticipated by Ito et al (U).

The Ito et al., teaches a method of detecting kidney fibrosis (i.e. a disease caused by overproduction of extracellular matrix) in diabetic patients by detecting CTGF and comparing said detection to a standard (Figure 5 and Table 1 in particular).

The prior art teachings anticipate the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 17 is rejected under 35 U.S.C. § 103 as being unpatentable over Ito et al., or WO 96/38172.

Ito et al., or WO 96/38172 have been discussed supra.

The claimed invention differs from the prior art teaching(s) only by the recitation of a kit.

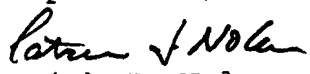
However, one skilled in the art would have recognized the usefulness of supplying a test kit for use in diagnostic assays. Test kits are compounds packaged for the convenience of the practitioner and are conventionally made to reproducibly obtain results under test conditions and it is conventional to assemble all necessary reagents, including antibodies, buffers and standards for the convenience of the practitioner and commercial expediency. Furthermore, the preamble reciting "A kit for ..." does not convey any patentable weight to the actual components of the kit itself.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to assay for the presence of CTGF to detect kidney fibrosis as taught by Ito et al., or WO 96/38172, and package the assay as a kit with the expectation that kits allow for ease and commercial reproducibility of known assays..

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

11. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

  
Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
May 21, 2001

PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER